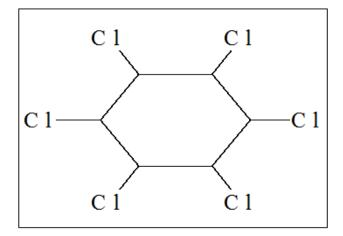


Draft Update of Human Health Ambient Water Quality Criteria:

alpha-BHC 319-84-6



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alpha-BHC 319-84-6

Draft

Office of Science and Technology
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Introduction: Plan and Scope of Update

Human health ambient water quality criteria (AWQC) are numeric values for pollutant concentrations in ambient waters that the U.S. Environmental Protection Agency (EPA) considers to be protective of human health. EPA periodically revises water quality criteria to ensure that they reflect the latest scientific knowledge. The current revisions of the criteria for alpha-BHC*, contained in this document, incorporate updated information regarding body weight, drinking water intake, fish consumption rate, and bioaccumulation. Updated body weight and drinking water intake data are identified in EPA's 'Exposure Factors Handbook: 2011 Edition' (USEPA, 2011). The bioaccumulation factor data is updated using EPA's Estimation Program Interface (EPI) Suite modeling program (USEPA, 2012a). The overall fish consumption rate and trophic level breakdowns are updated using EPA's 'Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)' (USEPA, 2014). Unless otherwise specified, all sources of information used in this update are from peer reviewed sources.

Note that the term "water quality criteria" can carry one of two possible meanings, depending on the section of the Clean Water Act (CWA) associated with the particular criteria at issue. "Water quality criteria" may refer to national water quality criteria recommendations issued under CWA § 304. "Water quality criteria" may also refer to water quality criteria components of water quality standards adopted by states, territories, or authorized tribes under CWA § 303.

National ambient water quality criteria recommendations for human health are issued by the EPA under CWA §304. They are based on the latest scientific information on the relationship between the effects of a constituent concentration and human health. Protective

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This compound is not currently registered as a pesticide by EPA.

assumptions are made regarding the potential human exposure intakes. These criteria do not reflect consideration of non-human health endpoints or economic impacts. Nor do they reflect the technological feasibility of meeting the chemical concentrations in ambient water. National ambient water quality criteria recommendations for human health are not automatically incorporated into water quality standards adopted by states, territories, or authorized tribes. Rather, they provide scientific information to states, territories and authorized tribes to assist them in adopting ambient water quality criteria for human health in water quality standards that meet CWA requirements. National ambient water quality criteria recommendations for human health are not regulations themselves and they do not impose legally binding requirements on EPA, states, territories, authorized tribes, or the public. States, territories, and authorized tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from EPA's national ambient recommended criteria for human health.

Ambient water quality criteria components of water quality standards are generally adopted by the states, territories, and authorized tribes themselves, under §303(c)(2). (In certain circumstances EPA also may promulgate this type of criterion itself, pursuant to §303(c)(4)). State ambient water quality criteria for human health represent a quality of water that sufficiently protects human health to support a designated use of the state, territory, or authorized tribe. Such criteria may be expressed in terms of constituent concentrations, levels, or narrative statements. Once ambient water quality criteria for human health are adopted by a state, territory, or authorized tribe into their water quality standards, they provide a basis for controlling discharges or releases of pollutants, for developing permit limits, assessing waters, and developing total maximum daily loads (TMDLs) for waters that do not meet the water quality standard. Ambient water quality criteria for human health have a regulatory impact once they have been adopted into water quality standards by the state, territory, or authorized tribe under § 303(c)(2) (or alternatively issued by EPA pursuant to § 303(c)(4)).

The water quality criteria at issue in this document are national ambient water quality criteria recommendations for human health issued under CWA § 304. Unless expressly indicated otherwise, all references to "criteria," "water quality criteria," "ambient water quality criteria (AWQC) recommendations," or similar variants thereof, are references to national ambient water quality criteria recommendations for human health.

Problem Formulation

Problem formulation provides a strategic framework for water quality criteria development by focusing on the most relevant endpoints and increasing the transparency of the effects assessment process. The structure of this criteria document is consistent with U.S. EPA's 'Framework for Human Health Risk Assessment to Inform Decision Making' (USEPA, 2012b).

In the development of AWQC, EPA currently follows the deterministic assessment methodology outlined in EPA's 'Methodology for Deriving Ambient Water Quality Criteria for

the Protection of Human Health (2000)' (USEPA, 2000), hereafter known as the 2000 Methodology. For the development of criteria for carcinogens that express a non-threshold, linear dose response, the 2000 Methodology takes into consideration exposure factors (body weight, drinking water intake, fish consumption, and bioaccumulation), the increased cancer risk due to exposure to the pollutant, and a 10^{-6} (or 1 in 1,000,000) risk level for the general population. The 10^{-6} risk level utilized in the derivation of the AWQC represents the water concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources. States and authorized tribes may consider adjusting exposure assumptions and related model inputs according to guidance in the 2000 Methodology, to assure that subpopulations are adequately protected if data are available.

Criteria Formulas- Analysis Plan

The following formulas are used to develop EPA's CWA Section 304(a) human health ambient water quality criteria. EPA develops criteria for ambient waters typically considering two routes of exposure. The first formula can be used to derive a human health criterion that assumes exposure through both the consumption of water and the consumption of aquatic organisms. The second formula can be used to derive a criterion that assumes exposure through the consumption of aquatic organisms, but not water. The use of one criterion over the other depends on the designated use of the water bodies in question (i.e. drinking water source and/or fishable waters).

EPA recommends inclusion of the drinking water exposure pathway for ambient surface waters where drinking water is a designated use for the following reasons: (1) Drinking water is a designated use for surface waters under the CWA, and therefore, criteria are needed to assure that this designated use can be protected and maintained. (2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment. (3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants. (4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment (USEPA, 2000).

EPA recommends the organism only criterion in those cases where the designated uses of a water body include only supporting fishable uses under Section 101(a) of the CWA, and thus, fish or shellfish for human consumption, but not as a drinking water supply source (e.g., non-potable estuarine waters) (USEPA, 2000).

The formulas for deriving the criteria values are as follows (USEPA, 2000):

For consumption of water and organisms:

AWQC (
$$\mu$$
g/L) = $[10^{-6} + / CSF (kg \cdot d/mg)] \times BW (kg) \times 1000 (μ g/mg) + (Eq. 1)
DI (L/d) + $\sum_{i=2}^{4} (FCR_i (kg/d) \times BAF_i (L/kg))$$

For consumption of organisms only:

AWQC (
$$\mu$$
g/L) = $\frac{[10^{-6} + CSF (kg \cdot d/mg)] \times BW (kg) \times 1000 (\mu g/mg)}{\sum_{i=2}^{4} (FCR_i (kg/d) \times BAF_i (L/kg))}$ (Eq. 2)

Where:

AWQC = ambient water quality criteria (at the 10⁻⁶ risk level)

CSF = cancer slope factor

BW = body weight

DI = drinking water intake

 $\sum_{i=2}^{4}$ = summation of values for aquatic trophic levels (TL) where the letter "i" stands for the

trophic levels to be considered, starting with TL 2 and proceeding to TL 4

FCR_i = fish consumption rate for aquatic trophic levels 2, 3, and 4 BAF_i = bioaccumulation factor for aquatic trophic levels 2, 3, and 4

The following sections identify each of the components of the formulas for the human health ambient water quality criteria and provide reference sources, previously used values when available, and the values to be used in the updated criteria.

Exposure Factors:

Body Weight

The updated recommended body weight (BW) is 80 kg which represents the mean weight for adults 21 years of age and older. This recommendation is found in EPA's 'Exposure Factors Handbook: 2011 Edition' in Chapter 8. It was based on data derived from the National Health and Nutrition Examination Survey (NHANES) 1999–2006 (USEPA, 2011). This body weight replaces the recommended standard weight for adults of 70 kg that was described in the 2000 Methodology which was approximated from the mean body weight of adults from the National Health and Nutrition Examination Survey (NHANES) III database (1988-1994) and a 1989 study by the National Cancer Institute (USEPA, 2000).

 $^{^{\}dagger}$ 10⁻⁶ or 1 in 1,000,000 risk level for the general population

^{‡ 1000} µg/mg is used to convert the units of mass into micrograms from milligrams.

Drinking Water Intake

The updated drinking water intake (DI) is 3 L/day, rounded from 3.091 L/day for consumer-only estimates of direct and indirect water ingestion based on NHANES 2003-2006 data for all sources of water at the 90th percentile for adults (≥21 years of age) (USEPA, 2011). Direct water is defined as water ingested directly as a beverage (from all sources); indirect water is defined as water added in the preparation of food or beverages, not including indirect consumption of bottled water. This recommended value is found in EPA's 'Exposure Factors Handbook: 2011 Edition' in Table 3-36. It replaces the drinking water intake standard of 2 L/day described in the 2000 Methodology which represented the 86th percentile for adults 20 years and older in the US Department of Agriculture's 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) analysis or the 88th percentile of adults in the National Cancer Institute study of the 1977-78 Nationwide Food Consumption Survey (USEPA, 2000).

Fish Consumption Rate

The updated fish consumption rate (FCR) for the general adult population is 22 grams/day (0.022 kg/day) (USEPA, 2014: *see Table 9a*). It represents the 90th percentile per capita consumption rate of freshwater and estuarine fish for the U.S. adult population 21 years of age and older based on the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Surveys (NHANES) conducted from 2003-2010. It replaces the FCR default of 17.5 grams/day, which represented an estimate of the 90th percentile per capita consumption rate of freshwater and estuarine fish for the U.S. adult population based on the U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intake by Individuals (CSFII) 1994-96 data (USEPA, 2002a).

As recommended in the 2000 Methodology, this update to the criteria distinguishes a trophic level (TL) breakdown of the fish consumption rate to provide a better representation of dietary exposure to fish at multiple trophic levels. An organism's trophic position in the aquatic food web can have an important effect on the magnitude of bioaccumulation of certain chemicals. The trophic levels are numbered 2, 3, and 4 and account for different categories of fish and shellfish species based on their position in the aquatic food web. TL2 accounts for benthic filter feeders, TL3 accounts for forage fish, and TL4 accounts for predatory fish.

In order to derive the trophic level breakdown of the 22 grams/day freshwater and estuarine FCR, the trophic level specific freshwater and estuarine FCR data sets for adults 21 years of age and older were identified (USEPA, 2014: see Tables 16a, 17a, and 18a). In each trophic level specific data set, the ratio of that trophic level's 90^{th} percentile FCR compared to the summation of all three trophic level specific 90^{th} percentile FCRs was applied to the 22 grams/day FCR used in this update. The trophic level ratios were calculated as follows: TL ratio = 90^{th} percentile FCR for the TL divided by the sum of the 90^{th} percentile FCRs for all TLs. TL2 = 7.6/21.3 = 0.3568 (35.68%), TL3 = 8.6/21.3 = 0.4038 (40.38%), and TL4 = 5.1/21.3 = 0.2394 (23.94%). Applying these ratios to the updated FCR of 22 grams/day result in trophic level breakdowns of TL2 = 8 grams/day (0.008 kg/day); TL3 = 9 grams/day (0.009 kg/day); and TL4 = 5

grams/day (0.005 kg/day). These resulting trophic level FCRs are well within the confidence intervals for each of the trophic level specific distributions' 90th percentiles and add to the total of 22 grams/day (USEPA, 2014).

Bioaccumulation Factor

Several attributes of the bioaccumulation process are important to understand when deriving national BAFs for use in setting national 304(a) criteria. First, the term "bioaccumulation" refers to the uptake and retention of a chemical by an aquatic organism from all surrounding media (e.g., water, food, sediment). The term "bioconcentration" refers to the uptake and retention of a chemical by an aquatic organism from water only. For some chemicals (particularly those that are highly persistent and hydrophobic), the magnitude of bioaccumulation by aquatic organisms can be substantially greater than the magnitude of bioconcentration. Thus, an assessment of bioconcentration alone may underestimate the extent of accumulation in aquatic biota for these chemicals. Accordingly, EPA's guidelines presented in the 2000 Methodology emphasize the measurement or estimation of chemical bioaccumulation by aquatic organisms (USEPA, 2000).

The bioaccumulation factors (BAF) have been estimated using EPA's Estimation Program Interface (EPI) Suite (USEPA, 2012a). The BCFBAFTM program within EPI Suite estimates fish bioaccumulation factors using octanol-water partition coefficients (K_{OW}) and biotransformation data from a model designed by Arnot and Gobas (2003). The model includes mechanistic processes for bioaccumulation such as chemical uptake from the water at the gill surface and from the diet, chemical elimination at the gill surface, fecal egestion, growth dilution and metabolic biotransformation. Other processes included in the calculations are bioavailability in the water column (only the freely dissolved fraction can bioconcentrate) and absorption efficiencies at the gill and in the gastrointestinal tract. The model requires the octanol-water partition coefficient (K_{OW}) of the chemical and the normalized whole-body metabolic biotransformation rate constant as input parameters to predict BAF values. Model predictions may be highly uncertain for chemicals that have estimated log K_{OW} values > 9. The model is not recommended at this time for chemicals that appreciably ionize, for pigments and dyes, or for perfluorinated substances (USEPA, 2012a).

For alpha-BHC, BAFs have been estimated using the EPI Suite model (USEPA, 2012a) as described above for trophic levels 2, 3, and 4. The estimated lower (TL2), mid (TL3), and upper (TL4) trophic level BAFs for alpha-BHC (log $K_{\rm OW}$ = 4.14) are 934.9 L/kg, 1,118 L/kg, and 1,935 L/kg wet-weight, respectively. These estimated BAFs replace the bioconcentration factor (BCF) of 130 L/kg used in the 2002 criteria derivations, which was calculated from a measured log octanol/water partition coefficient (log $K_{\rm OW}$) of 3.80 and represented all trophic levels (USEPA, 1980).

Hazard Identification and Dose Response: Cancer Slope Factor

Alpha-BHC is characterized as a class B2 probable human carcinogen following the 1986 EPA Guidelines for Carcinogen Risk Assessment (USEPA, 1986; USEPA, 1993).

The cancer slope factor (CSF) is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime oral exposure to an agent. The CSF for alpha-BHC is 6.3 per mg/kg·day (USEPA, 1993).

The principle study by Ito et al. (1973) chosen to calculate the cancer slope factor for alpha-BHC was based on development of hepatic nodules and hepatocellular carcinomas in mice orally exposed to alpha-BHC (USEPA, 1993).

Criteria Derivation- Analysis

Table 1 summarizes model inputs used to derive the 2014 updated human health ambient water quality criteria for alpha-BHC. Criteria calculations are presented below. These updated alpha-BHC criteria recommendations are based on the 2000 Methodology and updated exposure assumptions as described above (Exposure Factors).

Table 1. Summary of input parameters for 2014 human health ambient water quality criteria for alpha-BHC

Component		Value	Source	Input Characterization
CSF		6.3 per mg/kg·day	USEPA, 1993	an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent by ingestion
BW		80 kg	USEPA, 2011	mean weight for adults (≥21 years of age)
DI		3 L/day	USEPA, 2011	90 th percentile for adults (≥21 years of age)
FCR	TL2	0.008 kg/day	USEPA, 2014	90 th percentile consumption rate for the U.S. adult population (≥21 years of age)
	TL3	0.009 kg/day		
	TL4	0.005 kg/day		
BAF	TL2	934.9 L/kg	USEPA, 2012a	EPI Suite K _{OW} model estimated steady-state BAF values for non-ionic organic chemicals in 3 general trophic levels of fish in temperate environments (10°C)
	TL3	1,118 L/kg		
	TL4	1,935 L/kg		

For consumption of water and organisms:

AWQC (μ g/L) = [10⁻⁶ / CSF (kg·d/mg)] × BW (kg) × 1000 (μ g/mg) DI (L/d) + $\sum_{i=2}^{4}$ (FCR_i (kg/d) × BAF_i (L/kg))

```
= \frac{10^{-6} / 6.3 \text{ kg} \cdot \text{d/mg} \times 80 \text{ kg} \times 1000 \text{ µg/mg}}{3 \text{ L/d} + ((0.008 \text{ kg/d} \times 934.9 \text{ L/kg}) + (0.009 \text{ kg/d} \times 1,118 \text{ L/kg}) + (0.005 \text{ kg/d} \times 1,935 \text{ L/kg}))}
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= 0.000420 μg/L (rounded to 0.00042 μg/L because of significant figures, see 2000 Methodology)

For consumption of organisms only:

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AWQC (\mug/L) = \frac{[10^{-6} / \text{CSF (kg·d/mg)}] \times \text{BW (kg)} \times 1000 (\mu \text{g/mg})}{\sum_{i=2}^{4} (\text{FCR}_i (\text{kg/d}) \times \text{BAF}_i (\text{L/kg}))}

= \frac{10^{-6} / 6.3 \text{ kg·d/mg} \times 80 \text{ kg} \times 1000 \text{ \mug/mg}}{(0.008 \text{ kg/d} \times 934.9 \text{ L/kg}) + (0.009 \text{ kg/d} \times 1,118 \text{ L/kg}) + (0.005 \text{ kg/d} \times 1,935 \text{ L/kg})}

= 0.000466 \text{ \mug/L} (rounded to 0.00047 \text{ \mug/L} because of significant figures, see 2000 Methodology)
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The updated magnitude of the human health ambient water quality criteria for alpha-BHC at the 10^{-6} risk level are **0.00042** μ g/L (water and organism) and **0.00047** μ g/L (organism only) (Table 2). These updated criteria replace the previously published values (USEPA, 2002b).

Table 2. Summary of EPA's preciously recommended (2002) and updated (2014) human health ambient water quality criteria for alpha-BHC

	2002 Human Health AWQC	2014 Human Health AWQC
Water and Organism	0.0026 μg/L	0.00042 μg/L
Organism Only	0.0049 μg/L	0.00047 μg/L

These AWQC are meant to be protective of human health for the general adult population from an increased cancer risk due to exposure to alpha-BHC at a 10^{-6} or 1 in 1,000,000 risk level. The 10^{-6} risk level associated with the AWQC represents the concentration that would be expected to increase an individual's lifetime cancer risk from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources.

Criteria Characterization

The updated 2014 human health AWQC for alpha-BHC take into account current data on health effects and exposure input parameters, consistent with the 2000 Methodology. The updated 2014 human health AWQC for alpha-BHC are about an order on magnitude lower than EPA's previously recommended 2002 criteria; i.e. the water-and-organism criterion decreased from 0.0026 to 0.00042 μ g/L and the organism-only criterion decreased from 0.0049 to 0.00047 μ g/L (Table 2). The following paragraphs describe the individual influence of each of the revised model inputs and exposure assumptions on the overall change in value.

Body Weight

EPA's updated AWQC assume a higher body weight compared to the previously recommended 2002 criteria, reflecting a recent rise in average adult body weight among the U.S. population. The updated body weight assumption of 80 kg based on recent survey data from the 1999–2006 NHANES data is 10 kg greater than the previous recommendation of 70 kg. Assuming all other input parameters remain constant, a higher average body weight in the AWQC calculations (Eq. 1 and 2 above) results in higher AWQC. That is, as body weight increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure also increases.

Drinking Water Intake

The updated drinking water intake assumption is 3 L/day, which is higher than the previously recommended rate of 2 L/day. Assuming all other input parameters remain constant, a higher drinking water intake assumption in the AWQC calculations (Eq. 1 and 2 above) results in lower AWQC. That is, as drinking water intake increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

<u>Fish Consumption Rate</u>

The updated fish consumption rate is 22 g/day, divided into trophic level rates of 8 g/day, 9 g/day, and 5 g/day for trophic levels 2, 3, and 4, respectively, which is higher than the previously recommended rate of 17.5 g/day. Assuming all other input parameters remain constant, a higher fish consumption rate assumption in the AWQC calculations (Eq. 1 and 2 above) results in lower AWQC. That is, as fish consumption increase, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases.

Bioaccumulation Factor

The updated AWQC rely on EPI Suite model-estimated BAFs rather than the previously recommended BCF of 130 L/kg. The lower (TL2), mid (TL3), and upper (TL4) trophic level BAFs assumed in the updated criteria equations (Eq. 1 and 2 above) are 934.9, 1,118, and 1,935 L/kg wet-weight, respectively. Assuming all other input parameters remain constant, the higher ratios of fish tissue concentrations to water concentrations of alpha-BHC by aquatic organisms result in lower AWQC. That is, as bioaccumulation or bioconcentration of a contaminant in fish and shellfish increases, and thus overall exposure increases, the level of a contaminant in water at or below which negative health effects are not anticipated from a lifetime of exposure decreases. The utilization of a bioaccumulation factor rather than a bioconcentration factor better represents the amount of a contaminant accumulating in an organism because it accounts not only for the organism's exposure to the pollutant in the water column, but also from the food chain and surrounding environment as well as biotransformation of the pollutant

in the organism due to metabolic processes. The utilization of the three trophic levels of fish and shellfish consumed, as opposed to representing all trophic levels of fish and shellfish consumed by a single value, allows for better exposure representation, especially when pollutants bioaccumulate in significantly different amounts for organisms in different trophic levels at different positions in the food chain.

Additional routes of exposure to a particular pollutant besides exposure from water intake and fish consumption are possible and may be considered when setting criteria for a state or tribe. Possible additional routes include, but are not limited to, dermal exposure, inhalation exposure, marine fish and shellfish consumption (when not included in the fish consumption rate), and non-fish dietary exposures (fruits, vegetables, grains, meats or poultry). If scientific evidence exists which indicate that one or more of these routes pose a significant risk of exposure, states and authorized tribes are encouraged to ensure that subpopulations are adequately protected.

States, territories, and authorized tribes have the flexibility to develop criteria, on a sitespecific basis, that provide additional protection appropriate for highly exposed populations. EPA is aware that exposure patterns in general, and fish consumption in particular, vary substantially. EPA understands that highly exposed populations may be widely distributed geographically throughout a given state, territory, or authorized tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed populations. Thus, if a state, territory, or authorized tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national 304(a) criteria in particular, the state, territory, or authorized tribe may adopt more stringent criteria using alternative exposure assumptions (USEPA, 2000). Subpopulations that may be considered include, but are not limited to, recreational fishers, subsistence fishers, women of childbearing age, and children. When scientific data exist showing one of these subpopulations is at risk of greater exposure to the pollutant or are biologically more sensitive, then the relevant inputs should be considered in setting criteria. This could entail raising the fish consumption rate to a level more reflective of the subpopulation based on collected data or adjusting the body weight and drinking water intake.

Chemical Name / Synonyms

- alpha-BHC (CAS Number 319-84-6)
- alpha-benzenehexachloride
- Benzene hexachloride-alpha-isomer
- Cyclohexane, 1,2,3,4,5,6-hexachloro-, alpha-
- Cyclohexane, alpha-1,2,3,4,5,6-hexachloro-
- cyclohexane, 1,2,3,4,5,6-hexachloro-, alpha-isomer
- ENT 9,232
- alpha-HCH

- alpha-hexachloran
- alpha-hexachlorane
- Hexachlorcyclohexan
- alpha-hexachlorcyclohexane
- 1-alpha,2-alpha,3-beta,4-alpha,5-beta,6-beta-hexachlorocyclohexane
- Hexachlorocyclohexane, alpha-
- alpha-1,2,3,4,5,6-hexachlorocyclohexane
- alpha-lindane

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